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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/407,432	09/29/99	WORMAN H	JPW/GJG/YFL0

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EXAMINER	
SCHEINER, L	
ART UNIT	**PAPER NUMBER**
1648	8

DATE MAILED: 03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/407,432	Worman et al.
Examiner	**Group Art Unit**
Laurie Scheiner	1648

☒ Responsive to communication(s) filed on *Jan 23, 2001*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-32, 45, 70, and 71* is/are pending in the applicat

Of the above, claim(s) *20-32, 45, 70, and 71* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-19* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Claims 1-32, 45, 70 and 71 are pending in this application. Applicant's election of Group II (claims 1-19) and the species drawn to treatment using the DEAD-box protein in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). That is, applicants have not adequately argued that the respective methods are not used together, and have different modes of operation, different functions, and different effects. The Groups, in fact, are not at all similar. For example, Invention I employs HCV core plus a second compound to detect inhibitory activity of a third compound; whereas, Invention III employs HCV core protein to inhibit cancer cell growth. Applicants additionally contend that a burden would not be imposed by searching all Groups since the art pertinent to the respective Inventions would overlap. The examiner does not agree since the research in this area is fairly extensive. As such, claims 20-32, 45, 70 and 71 are withdrawn from consideration as being drawn to a non-elected invention. Moreover, the reading of claims 1-19 will be strictly limited to the elected species (treatment using DEAD-box protein).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen,* 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim,* 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 1-19

are essentially drawn toward a method of treating or preventing hepatitis C virus infection in a human subject by administering an effective amount of a DEAD-box protein to the subject, wherein the DEAD-box protein is capable of specifically binding to the HCV core protein so as to inhibit HCV replication. A pharmaceutically acceptable carrier is also contemplated. The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.,* 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Werthheim, et al.,* 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll,* 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga,* 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly,* 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano,* 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). *In re Bell,* 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993). *In re Deuel,* 34 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995).

Applicants' disclosure fails to provide adequate written support for the invention as claimed. That is, applicants' claims encompass a method of treating or preventing hepatitis C virus infection in a human subject by administering an effective amount of a DEAD-box protein to the subject, wherein the DEAD-box protein is capable of specifically binding to the HCV core protein so as to inhibit HCV replication. Again, the disclosure fails to provide an adequate written description for subject matter supporting the *in vivo* DEAD-box inhibition of HCV. Applicants'

claims are drawn to a treatment based on a hypothesis of inhibition of viral replication which is unsupported by the specification. Moreover, the theory that the binding of DEAD-box protein to core protein may actually enhance viral replication may be more likely. Mere interaction or binding between HCV core protein and DEAD-box protein in an *in vitro* binding assay is insufficient -especially since a cell culture system is not currently available for HCV. Again, the binding may actually stimulate viral replication by DEAD-box protein altering viral genomic RNA structure in viral particles in newly infected cells. Again, the consequences of HCV core protein on host cell physiology under natural conditions of infection is difficult to determine since an appropriate cell culture system does not exist.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth above, claims 1-19 are drawn toward a method of treating or preventing hepatitis C virus infection in a human subject by administering an effective amount of a DEAD-box protein to the subject, wherein the DEAD-box protein is capable of specifically binding to the HCV core protein so as to inhibit HCV replication, which is not adequately supported by the disclosure. Applicants are reminded of the legal considerations governing enablement determinations pertaining to undue experimentation as disclosed in *In re Wands,* 8 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer,* 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The

disclosure fails to provide adequate guidance pertaining to these considerations. Moreover, the prior art is unpredictable and fails to provide any guidance pertaining to the functional requirements of the instant method. Additionally, the prior art teaches away from the hypothesis which applicants have based their claims upon. Thus, conclusions drawn in the specification with respect to *in vitro* experiments are not supported by the art. That is, Owsianka and Patel (Virology **257**, 330-340, 1999) when discussing a similar experimental model teach that it is important to realize that the model system in which their studies were completed is artificial. Also, they teach that DDX3 may be sequestered from its normal function by HCV core to cooperate directly in some aspect of the viral life cycle. "If DEAD-box proteins can be thought of as mechanical devices for carrying out various RNA-related processes, then DDX3 could be envisioned as a molecular motor that the virus needs to drive its own machinery for manipulating RNA. It could be involved in the expression, replication, or packaging of viral RNA." Thus, the art is not supportive of applicants' hypothesis that the binding of core protein by DEAD-box protein *in vivo* inhibits HCV viral replication.

In summation, the disclosure fails to provide sufficient guidance pertaining to the method claimed. Accordingly, when all the aforementioned considerations are taken together, it would clearly require undue experimentation to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

Laurie Scheiner/LAS
March 23, 2001

LAURIE SCHEINER
PRIMARY EXAMINER